

JAPANESE

[JP,10-273436,A]

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CLAIMS DETAILED DESCRIPTION TECHNICAL  
FIELD PRIOR ART EFFECT OF THE INVENTION  
TECHNICAL PROBLEM MEANS EXAMPLE

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[Translation done.]

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**DETAILED DESCRIPTION**

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[Detailed Description of the Invention]

[0001]

[Field of the Invention]Digestion with this invention preferred as drugs, foodstuffs, health food, etc. is related with few easy and adhesive soft capsules.

[0002]

[Description of the Prior Art]Neither a child nor the old man may be unable to swallow solid oral administration agents, such as a tablet, a pill, and a capsule, or may be difficult to take. An emergency like [ at the time of the fit of angina pectoris ] is expected the drugs of the pharmaceutical form to which it can take easily and an active principle can be made to emit promptly within the mouth.

[0003]The thing which are beginning to be observed with diversification of taste by the feel in inner mouth, such as

foodstuffs, these days, for example, is elastic like nata de coco on the other hand and which it bit and the feeling became a boom is also fresh in memory.

[0004]By the way, there is a soft capsule agent as a solid oral administration agent which has elasticity. Contents are made to include in the usual soft capsule agent in the gelatin coating which mixed gelatin, a plasticizer, and water, was dissolved and was spread thinly. In the coating of a soft capsule, a plasticizer is added 30 to 40% of the weight to gelatin, and it is made to dry generally until the moisture content in a coating will be 5 to 10 % of the weight, in order to prevent modification and adherence of a capsule.

[0005]However, since it is designed dissolve within an intestinal tract and emit contents, it is hard, and big power is needed for crunching by inner mouth, and the soft capsule of such a formula is not suitable as an object for digestion.

[0006]Since the adhesion of soft capsules, and a soft capsule and a container will increase and preservation stability will fall, if it does so although what is necessary is just to increase the loadings of a plasticizer in order to make a soft capsule agent softer, While it is not suitable for the climate of heat and high humidity like [ of Japan ], there is a problem of producing the stickiness to a gear tooth etc. at the time of digestion.

[0007]

[Problem(s) to be Solved by the Invention]Therefore, while being able to crunch this invention easily by inner mouth, there is little adhesion, and also an object of this invention is to provide the soft capsule for digestion which is excellent also in solubility.

[0008]

[Means for Solving the Problem]this -- the actual condition -- setting -- this invention -- a person -- \*\* -- wholeheartedly -- research -- having piled up -- a result -- a coating -- inside -- being specific -- a plasticizer -- usual -- gelatin -- a coating -- using -- having -- quantity -- several -- a time -- adding -- while. By blending the cellulose of insoluble in water nature, a soft and good thing acquired for few adhesive soft capsule agents biting and having a feeling was found out, and this invention was completed.

[0009]Namely, one sort as which, as for this invention, a coating is chosen from - (b1) (b3) of 100 - 600 weight section in total to the following ingredient (A), (B), and (C)

(A) gelatin (B) gelatin 100 weight section, or two sorts or more of plasticizer (b1) glycerin (b2) D-sorbitol, sucrose, A soft capsule agent for digestion containing the glycol (C) insoluble in water nature cellulose chosen from sugars (b3) propylene glycol and a polyethylene glycol which are chosen from mannitol, fructose, sucrose alcohol, and isomerized sugar is provided.

[0010]

[Embodiment of the Invention]In this invention, with "gelatin", gelatin, acid gelatin, alkaline gelatin, These all can be used including all, such as a derivative of peptide gelatin, low molecule gelatin, and gelatin, as a (A) ingredient of the coating of the soft capsule agent for digestion of this invention.

[0011]Although one sort chosen from glycerin (b1), sugars (b2), and (b3) glycols or two sorts or more are used as a plasticizer of the (B) ingredient of a coating, It is preferred to use glycerin at least (b1) as one of the plasticizer components in this invention, and if the ease of molding is especially taken into consideration, it is preferred to use together glycerin (b1) and at least one sort of the sugars which are other plasticizer components (b2), and (b3) glycols.

[0012]Especially the loadings of the plasticizer in a coating exceed 150 weight sections 100 to 600 weight section as the plasticizer whole quantity to gelatin 100 weight section of the (A) ingredient, and its 300 or less weight sections are preferred. If a capsule becomes hard in less than 100 weight sections and loadings exceed 600 weight sections, it will become soft, but molding becomes difficult.

[0013](B) When using glycerin of (b1) alone as an ingredient, especially the amount used has 120 - 200 preferred weight section 100 to 300 weight section to gelatin 100 weight section of (A).

[0014]In this invention, although what is chosen from D-sorbitol, sucrose, mannitol, fructose, sucrose alcohol, and isomerized sugar is used as sugars of (b2), in order to give the sweet taste at the time of digestion, D-sorbitol, sucrose, and mannitol are preferred. Adhesive D-sorbitol from a point and mannitol of lowness when it adds to high concentration are preferred. When using sugars alone as a plasticizer, especially the amount used has 120 - 200 preferred weight section 100 to 300 weight section to gelatin

100 weight section of (A).

[0015](b1) If glycerin and sugars (b2) are used together, it excels in compatibility and plasticizer concentration can be raised. When using glycerin and sugars together, it is preferred to carry out 50-150 weight-section combination of 50 to 250 weight section and the sugars for glycerin especially 30 to 300 weight section 50 to 300 weight section to gelatin 100 weight section.

[0016]In this invention, what is chosen from propylene glycol and a polyethylene glycol is used as glycols of (b3). Especially as a polyethylene glycol, the thing of the weight average molecular weight 400-4000 is preferred. These glycols have strong hygroscopicity, and as for an addition, since the handling after shaping becomes difficult, it is preferred that it is seldom too large. When using glycols alone as a plasticizer, especially the amount used has 120 - 180 preferred weight section 100 to 200 weight section to gelatin 100 weight section of (A).

[0017](b1) Concomitant use of glycerin and glycols (b3) will obtain a very soft gelatin coating. When using propylene glycol together with glycerin as (b3), it is preferred to carry out 40-100 weight-section combination of 50 - 120 weight section and the propylene glycol for glycerin especially 20 to 300 weight section 40 to 200 weight section to gelatin 100 weight section. When using a polyethylene glycol together with glycerin as (b3), it is preferred to carry out 50-100 weight-section combination of 60 - 80 weight section and the polyethylene glycol for glycerin especially 40 to 200 weight section 50 to 100 weight section to gelatin 100 weight section.

[0018]In using together three persons of glycerin (b1), sugars (b2), and (b3) glycols, It is preferred to carry out 60 to 150 weight section for glycerin, and to carry out 50-100 weight-section combination of 40 to 80 weight section and the glycols for sugars 20 to 120 weight section 30 to 130 weight section especially 50 to 200 weight section to gelatin 100 weight section.

[0019]As insoluble in water nature cellulose of the (C) ingredient of a coating, crystalline cellulose, ethyl cellulose, hydroxypropylcellulose, and starch are mentioned. Especially the loadings of insoluble in water nature cellulose have 25 - 75 preferred weight section five to 100 weight section to gelatin 100 weight section of the (A) ingredient.

Since the adhesion of a capsule is not fully improved for the loadings of insoluble in water nature cellulose by less than five weight sections to gelatin 100 weight section, capsules or a capsule, and a container adhere at the time of preservation and a feeling of adhesion in inner mouth arises, it is not desirable. Molding will become difficult if the loadings of insoluble in water nature cellulose exceed 100 weight sections to gelatin 100 weight section.

[0020] Into the coating of the soft capsule agent for digestion of this invention, colorant, an antiseptic, disintegrator, a surface-active agent, an aromatic, corrigent, an odor-masking agent, etc. can be blended if needed in addition to the above (A) - the (C) ingredient.

[0021] The soft capsule agent for digestion of this invention can be manufactured according to the manufacturing method of the usual soft capsule agent. That is, capsule contents are poured in and it is manufactured by carrying out cooling solidification at the same time it sends into a soft capsule manufacturing machine the constituent for capsule hides which consists of an optional component of (A) - (C) ingredient which carried out heat melting, for example, water, and others and changes it according to a metallic mold, extending to a sheet shaped.

[0022] The soft capsule agent for digestion of this invention can be used conveniently for foodstuffs, such as drugs and confectionery, health food, etc.

[0023]

[Example] Although an example is given and this invention is explained still in detail hereafter, this invention is not limited to these.

[0024] Gelatin sheets were produced from the gelatin constituent of the presentation of example of examination 1 versatility, and the adhesion of the feel in inner mouth, the taste, a feeling of stickiness, and sheets was evaluated.  
Production> (1) of <gelatin sheets Purified water optimum dose and (JP) the concentrated glycerin 100g were measured to a 1-l. beaker, and it mixed to it. Next (JP), stirring 100 g of gelatin, in addition, it warmed by about 60 \*\* water bath, gelatin was dissolved uniformly, and the gelatin constituent 1 was obtained.

[0025](2) D-sorbitol syrup (JP) 150g and (JP) the concentrated glycerin 50g were measured to a 1-l. beaker, and also purified water optimum dose was added and it

mixed. 50 g of crystalline cellulose (JP) (Avicel, Asahi Chemical Industry Co., Ltd. make) was added to this liquid, and it fully mixed. Next (JP), stirring 100 g of gelatin, in addition, it warmed by about 60 \*\* water bath, gelatin was dissolved uniformly, and the gelatin constituent 2 was obtained.

[0026](3) Purified water optimum dose, the concentrated glycerin (JP) 80g, and the white soft sugar 40g were measured to a 1-l. beaker, and it mixed to it. White soft sugar was dissolved thoroughly, putting a beaker into not less than 80 \*\* boiling water, and stirring it. After cooling a solution radiationally to a room temperature, 40 g and 40g of polyethylene glycols 4000 were added, and churning and the dissolution of the polyethylene glycol 400 were done, and also (JP) 50 g of crystalline cellulose (Avicel, Asahi Chemical Industry Co., Ltd. make) was added, and it was made to distribute. Next, stirring 100 g of amber-ized gelatin (JP,55-138457,A), in addition, it warmed by about 60 \*\* water bath, amber-ized gelatin was dissolved uniformly, and the gelatin constituent 3 was obtained.

[0027](4) It was made to distribute in addition, weighing 80 g and 70g of polyethylene glycols 4000 to a 1-l. beaker, and agitating and dissolving purified water optimum dose, the concentrated glycerin (JP) 60g, and the polyethylene glycol 400 in it, and also stirring 50 g of crystalline cellulose. Next (JP), stirring 100 g of gelatin, in addition, it warmed by about 60 \*\* water bath, gelatin was dissolved uniformly, and the gelatin constituent 4 was obtained.

[0028](5) (1) The gelatin constituents 1-4 obtained by - (4) were uniformly poured on the board (about 80 cm x 80 cm) of a plastic, it dried at 25-30 \*\*, and the gelatin sheets of about 0.5-mm thickness were obtained. The chip (about 1 cm x 1 cm) was cut out from gelatin sheets, and the gelatin sheets 1-4 were obtained.

[0029]<Evaluation> By five persons' panelist, organic-functions evaluation was performed about the feel in the inner mouth of each gelatin sheets, a feeling of stickiness, etc., and each gelatin sheets were sealed in the glass bottle, and the adhesion of the sheets at the time of saving for one month at 40 \*\* and a sheet, and a container was evaluated. This result is shown below.

[0030]Gelatin sheets 1 (comparison article) : Although it was softly elastic, there was a feeling of stickiness in inner

mouth. Adhesion of the sheet after preservation was remarkable.

[0031]Gelatin sheets 2: It was softly elastic, and at the refreshing feel, it bit, there is also no stickiness in inner mouth, and it had still more moderate sweet taste. There is no adhesion of the sheet after preservation and it was carrying out dry one.

[0032]Gelatin sheets 3: It was softly elastic, and at the refreshing feel, it bit, there is also no stickiness in inner mouth, there is still more moderate sweet taste, and it excelled also in the solubility in inner mouth. There is no adhesion of the sheet after preservation and it was carrying out dry one.

[0033]Gelatin sheets 4: It was softly rich in elasticity, and it bit and there was also no stickiness in the inner mouth in a refreshing feel. There is no adhesion of the sheet after preservation and it was carrying out dry one.

[0034]By the method shown in one or less comparative example, the gelatine capsule agent which has a coating of the same presentation as the gelatin sheets 1 of the example 1 of an examination was prepared. About 8.5 kg of purified water and 5.0 kg of concentrated glycerin were put in and stirred on a 200-l. stainless steel tank. Next, after putting in and stirring 5.0 kg of gelatin and swelling gelatin enough, gelatin was dissolved in the stainless steel tank through 60-70 \*\* warm water. Subsequently, it defoamed under decompression and used for molding of a gelatine capsule. Using the rotary system automatic briquetting machine, molding of a capsule selected the No. 5 oval to the model, and performed it. It dried in a 20-25 \*\* drying room so that it might be filled up with 300 mg of medium-chain-fatty-acid triglyceride as contents of a capsule and the moisture of a capsule hide might be 6 to 10 % of the weight after molding, and the soft capsule agent 1 (comparison article) was obtained.

[0035]By the method shown in one or less example, the gelatine capsule agent which has a coating of the same presentation as the gelatin sheets 2 of the example 1 of an examination was prepared. About 4.5 kg of purified water, 2.5 kg of concentrated glycerin, and 7.5 kg of D-sorbitol syrup were put in and stirred on a 200-l. stainless steel tank. 2.5 kg of crystalline cellulose (Avicel PH101, Asahi Chemical Industry Co., Ltd. make) was added to this liquid,

and it was distributed. Next, in addition, gelatin was dissolved in the tank through 60-70 \*\* warm water, stirring 5.0 kg of gelatin. Subsequently, it defoamed under decompression and the gelatin solution was obtained.

Except using this gelatin solution, capsule molding was performed like the comparative example 1, and the soft capsule agent 2 (this invention article) was obtained.

[0036]By the method shown in two or less example, the gelatine capsule agent which has a coating of the same presentation as the gelatin sheets 3 of the example 1 of an examination was prepared. About 5.0 kg of purified water, 4.0 kg of concentrated glycerin, and 2.0 kg of white soft sugar were \*\*\*\*-picking-mixed on a 200-l. stainless steel tank. Next, white soft sugar was dissolved, stirring through 60-70 \*\* warm water on a stainless steel tank. After cooling a solution to near a room temperature through tap water, 2.0 kg and 2.0 kg of polyethylene glycols 4000 were added, and the polyethylene glycol 400 was stirred and dissolved. This liquid was made to distribute 2.5 kg of crystalline cellulose (Avicel PH101, Asahi Chemical Industry Co., Ltd. make). Next, in addition, through and amber-ized gelatin were gradually dissolved for 60-70 \*\* warm water in the stainless steel tank, stirring 5.0 kg of amber-ized gelatin (JP,55-138457,A). Subsequently, it defoamed under decompression and the gelatin solution was obtained. Except using this gelatin solution, capsule molding was performed like the comparative example 1, and the soft capsule agent 3 (this invention article) was obtained.

[0037]By the method shown in three or less example, the gelatine capsule agent which has a coating of the same presentation as the gelatin sheets 4 of the example 1 of an examination was prepared. About 5.0 kg of purified water is thrown into a 200-l. stainless steel tank, 4.0 kg and 3.5 kg of polyethylene glycols 4000 were added, and 3.0 kg of concentrated glycerin and the polyethylene glycol 400 were stirred and dissolved. It was made to distribute in addition, stirring 2.5 kg of crystalline cellulose (Avicel PH101, Asahi Chemical Industry Co., Ltd. make) in this liquid. Next, 5.0 kg of gelatin was put in and stirred and gelatin was dissolved in the tank through 60-70 \*\* warm water.

Subsequently, it defoamed under decompression and the gelatin solution was obtained. Except using this gelatin solution, capsule molding was performed like the

comparative example 1, and the soft capsule agent 4 (this invention article) was obtained.

[0038]About each soft capsule agent obtained in the example of examination 2 comparative example 1, and Examples 1-3, by five persons' panelist. Organic-functions evaluation was performed about the feel in inner mouth, a feeling of stickiness, etc., and each 50 gelatine capsules were sealed in the glass bottle, and the adhesion of the capsules at the time of saving for one week at 40 \*\* and a capsule, and a container was evaluated. This result is shown below.

[0039]Soft capsule agent 1 (comparison article) : Although it was soft and elastic, it was sticky by inner mouth and admiration was sensed. Capsules did not adhere and separate in the bottle after preservation.

[0040]Soft capsule agent 2 (this invention article) : It is soft like a comparison article, and is elastic, and there is also no feeling of stickiness, and digestion had easy sweet taste moderate [ both ]. Adhesion of a capsule does not have after preservation and it was carrying out dry one.

[0041]Soft capsule agent 3 (this invention article) : It is soft like a comparison article, and is elastic, and there is also no feeling of stickiness, it excelled also in solubility, and digestion had easy sweet taste moderate [ both ]. Adhesion of a capsule does not have after preservation and it was carrying out dry one.

[0042]Soft capsule agent 4 (this invention article) : It was soft like the comparison article, and it is elastic, and there was also no feeling of stickiness, it excelled also in solubility, and digestion was easy. Adhesion of a capsule does not have after preservation and it was carrying out dry one.

[0043]

[Effect of the Invention]While being able to crunch easily the soft capsule agent for digestion of this invention by inner mouth, there is little adhesion and also it is excellent also in solubility.

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[Translation done.]